NWDA Suspicious Order Monitoring System

NWDA SUSPICIOUS ORDER MONITORING SYSTEM

I. BACKGROUND

It is the responsibility of the wholesaler to design and operate a system which will disclose to the wholesaler suspicious orders of controlled substances. The monitoring and reporting of suspicious orders of controlled substances can be performed by either computerized methods or a manual system depending upon the wholesaler's preference and capability. The requirement is to monitor individual orders by measuring dosage units within a each order and to examine for suspicious volumes. Special emphasis should be placed on unusual or sudden increases with the volume of invoice lines processed by the average wholesaler. This task becomes increasingly difficult, as the number of products and dosage sizes increase.

The National Wholesale Druggists' Association voluntarily began working with the Department of Justice, Drug Enforcement Administration (DEA) in establishing controls clearly aimed at reducing or eliminating illegal product distribution. The following is a general description of the system.

II. DEFINITION OF SUSPICIOUS ORDERS

Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency.

III. PURPOSE OF THE SUSPICIOUS ORDER MONITORING SYSTEM

The purpose of this suspicious order monitoring system is to:

1. Establish suspicious order monitoring criteria which will track product movement between a wholesale distribution point and a pharmacy shipping location.

2. Provide flexibility to permit different monitoring criteria based on customer classification (e.g., hospitals vs. retail).

3. Provide flexible monitoring criteria to be used that is dependent on DEA schedule classifications, Schedule II and III (ARCOS[1] items) vs. Schedule IIIN through V (non-ARCOS items).

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[1]DEA requires monthly reporting of all incoming and outgoing controlled drug transactions and inventories on a national system known as the Automating of Reports and Consolidated Order Systems (ARCOS), as described in The ARCOS Reporting Manual. This manual is available from the DEA, Washington D.C.

4. Provide a method of monitoring purchases across vendor product lines and product sizes.

5. Establish a standard system of reporting across wholesale distribution centers thus providing the DEA at district and federal levels with similar tools.

IV. SYSTEM DESCRIPTION

The suspicious order monitoring system will accumulate product sales on a monthly and year-to-date basis. Customer classification averages are calculated for hospitals, retailers, distributors, dispensing physicians and nursing homes and clinics as separate customer segments.

V. USE OF DEA BASE CODES

The DEA has established a four position base code number for each base ingredient. For example, DEA base code 9050 identifies codeine. At the time of writing, there were 58 base ingredients which had been identified by the DEA. All schedule items (II through V) which contain base ingredients will be identified by the DEA. The list of these items will be distributed through the NWDA to wholesalers implementing this monitoring system. Each schedule product will be identified by a DEA base code, base name, NDC number, and gram equivalent. Updated information for new drug base ingredients and base weights will be coordinated between NWDA and DEA on a quarterly basis.

This approach allows product distribution monitoring at base code level as opposed to the monitoring of stock-keeping units. For instance, if a customer were to switch from one analgesic with codeine to another, he will not escape detection under this system. Likewise, a customer who legitimately may switch stock packs will not falsely trigger a suspicious order.

VI. MONTHLY CALCULATIONS

The suspicious order monitoring system should review all purchase transactions involving DEA schedule classifications II through V on a monthly basis.

The program reads the previous 12 month sales history file to calculate averages for reporting criteria. Variance levels are used with the calculated averages to insure that only potential abusive purchases are reported.

A. Rolling 12 Months Grams Sold = Current Year's Total Grams Sold

Product Gram Equivalent–The DEA, working with manufacturers, has established a gram equivalent for all schedule products (II-V). For example, an analgesic with codeine sold in a bottle of 100's may contain ten grams of codeine, whereas a bottle of 1,000 would contain one hundred grams. By adding all products purchased by a customer that contain base code 9050/codeine, average purchases can be determined within a specified time frame or classification of customers.

B. Number Of Customers Who Purchased = Number Of Invdividual Customers Who Purchased the Total Grams Sold

Customer Classification–The DEA has identified customer groupings which must be monitored separately due to differences in their buying/dispensing characteristics. They are hospitals, retail pharmacies, distributors, dispensing physicians, nursing homes and clinics. Utilizing these classifications, the DEA may establish separate monitoring controls within each customer classification.

Annual Average	=	Current 12 Months Total GM Sold ÷ Number of Customers Who Purchased
Monthly Average Total GM Sold	=	Annual Average Total GM Sold ÷ 12
Current Month Ingredient Limit	=	Monthly Average Total GM Sold x NN.NN (note: NN.NN will be provided by the DEA)
Number of Customers Exceeding NN.NN Times Monthly Average	=	Count of Customers
Quantity Sold	=	Invoice Stock Keeping Units Sold
Total GM Purchased	=	Quantity Sold x Items GM Factor
Customer Total	=	Accumulated Total GM Purchased

C. **Ingredient Limit = Current Month Ingredient Limit**

Ingredient Limits–The DEA may supply ingredient limits in any or all of the following methods:

1. Customer classification and further divided by ARCOS and non-ARCOS. Utilizing this method, the suspicious order monitoring system will establish customer averages by classification taking into account a rolling twelve month sales period computing a monthly average per classification. Those customers exceeding the gram equivalent limits are to be reported by customer classification.

2. Base code limits. This technique provides further definition of limit variance reporting by base code within a customer classification.

Monthly reporting based on DEA defined criteria will be made from each wholesale distribution center to the DEA field division.

VII. REPORTING LEVELS

Two levels of reporting are available through the suspicious order monitoring system. The first level is a summary report identifying those pharmacy shipping locations which have experienced variances from DEA order monitoring standards. The second level is detail reporting and is optional at the request of the DEA. It identifies all the product sales within a given month whose variances create a summary report. Wholesalers are required to provide records retention of these two reporting systems for up to 24 months.

A. Variance Reporting Options

For reporting, the suspicious order monitoring system will provide the following options to be used at the discretion of the DEA.

1. Customer Classifications

The DEA may identify separate variance reporting based on customer classification. These customer classifications are to be maintained by the wholesale distribution center. The classifications are as follows.

(a) hospitals
(b) retailers
(c) distributors
(d) dispensing physicians
(e) nursing homes
(f) clinics

2. DEA Schedule Classification

The wholesale distribution center will provide separate variance monitoring based on the following DEA schedule classifications:

(a) Schedule II and III (ARCOS Items)
(b) Schedule IIIN, IV, and V (Non-ARCOS Items)

3. DEA Base Code Variance Factor

Each distribution center will provide the capability of altering the variance factor by DEA base code number by both customer classification and DEA schedule classification.

B. Summary Report

1. General Description

The suspicious order monitoring variance report is produced monthly and displays customers who have experienced variances based on DEA defined reporting criteria.

2. Required Data Elements

(a) Distribution center name and location
(b) Reporting period
(c) DEA schedule class contained on the report (example: schedule items II and III)
(d) Variance percentage by schedule class/account type/DEA base code.
(e) Customer name and address
(f) Customer DEA number
(g) Customer account type (example: hospital/other)
(h) DEA base code number
(i) DEA base code name
(j) DEA base code percent variance criteria (optional if used by the DEA)
(k) Account type monthly average grams purchased per base code
(l) Customer current month actual grams purchased
(m) Variance indicator
(n) Optional fields:

- rolling twelve month grams purchased by base code within customer account
- customer average by base code over a twelve month period

3. Reporting Sequence

The reporting sequence is optional at the discretion of the Distribution Center. However, within major sorting sequence must summarize at the customer and DEA base code levels.

C. Detail Reporting

1. General Description.

The detail report is used as an investigative tool by the DEA. Distribution centers must have detail reporting capabilities availabile to produce reports upon request from the DEA. This may be accomplished by designing a processing system which can extract and report required information or by generating a monthly report and sending it whole or in part upon request by the DEA.

2. Required Data Elements

(a) Distribution center name and location/DEA number
(b) Reporting period
(c) Customer name and address
(d) Customer DEA number
(e) DEA base code number
(f) DEA base code name
(g) Invoice detail
- invoice number
- invoice date
- quantity sold
- item description
- NDC number
- gram equivalent

(h) Total grams by base code
(i) Items e-h are repeated for each base code variance
(j) Items c-h are repeated for each account which exceeded the variance percentages

2. Reporting Sequence

The reporting sequence is optional at the discretion of the distribution center. However, information must be summarized at the customer level.

VIII. REPORT DISTRIBUTION

A. Summary Report

1. First copy is sent to the DEA regional office during the first week of each new month covering all sales for the previous month.

2. Second copy is to be retained within the distribution center for 24 months.

B. Detail Report

1. First copy is to be retained by the distribution center for 24 months.

2. Second copy is to be forwarded to the DEA in whole or in part based on their request.

C. Microfiche

Due to the magnitude of information contained in these reports, microfiche may be used in place of hard copy at the discretion of the distribution center. This media is an acceptable alternative for use by the DEA, but requires DEA approval. Microfiche copies, either on film or made from a reader printer, are also acceptable options.

IX. SINGLE SUSPICIOUS ORDERS

Single orders of unusual size or deviation must be reported immediately. The submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting these single excessive or suspicious orders. DEA has interpreted "orders" to mean prior to shipment.

X. SUMMARY

The data elements listed on the preceding pages provide the necessary gram equivalent information in order to establish a record of purchases on an average basis among the customer classification or individual account. This information will be disseminated by the NWDA. The base code limits will be obtained from local DEA offices working with those organizations utilizing the Suspicious Order Monitoring System.

Letters From DEA Approving The Format

U.S. Department of Justice
Drug Enforcement Administration

Washington, D.C. 20537

APR 27 1984

Mr. Ronald J. Streck
Vice President of Government Affairs
National Wholesale Druggists'
Association
P. O. Box 238
Alexandria, Virginia 22313

Dear Mr. Streck:

I want to take this opportunity to thank you, Mr. David Prins (Twin City Wholesale), and Mr. Robert Bone (Bergen Brunswig) for meeting with Mr. David Walkup and me on April 13, 1984.

The NWDA's draft format for a suspicious order monitoring system provides an excellent framework for distributor registrants to "...design and operate a system to disclose to the registrant suspicious orders of controlled substances." [21 CFR 1301.74(b).] However, I am compelled to note, as I have in our previous discussions, that any automated data processing system may provide the means and mechanism for compliance when the data is carefully reviewed and monitored by the wholesaler. As previously discussed, an after-the-fact computer printout of sales data does not relieve a registrant of its responsibility to report excessive or suspicious orders when discovered. I am enclosing a copy of your draft with my pen-and-ink changes.

Again, I want to thank the NWDA for this pioneering effort. This reporting format should provide an excellent framework

Mr. Ronald J. Streck

from which member wholesalers can work closely with DEA in a spirit of cooperation. Please feel free to call me if you have any additional questions.

Sincerely,

G. Thomas Mitchell Acting Chief
Diversion Operations Section

Enclosure

MAY 16 1984

Ronald J. Streck
Vice President
Government Affairs
National Wholesale Druggists Association
P. O. Box 238
Alexandria, Virginia 22313

Dear Mr. Streck:

I want to take this opportunity to follow up on my April 27, 1984 letter and the recent NWDA Government Affairs Committee meeting that was attended in part by Mr. David Walkup of my staff. In order to clarify any misinterpretations, I want to assure you that DEA fully supports the NWDA effort to introduce a uniform reporting system among its members. This system, as proposed, will meet the reporting requirements of 21 CFR 1301.74(b). However, I want to make it clear that the submission of a monthly printout of after-the-fact sales will not relieve a registrant from the responsibility of reporting excessive or suspicious orders. DEA has interpreted "orders" to mean prior to shipment.

It is my understanding that Mr. Walkup will be attending the two NWDA regional meetings scheduled later this month and in early June. He will be discussing DEA reporting requirements under 21 CFR 1301.74(b) and will be available for a question and answer session.

If you have any further questions, please give me a call.

Sincerely,

G. Thomas Gitchel, Acting Chief
Diversion Operations Section